

Malta, 15 June 2009  
Circular No. P09/2009

Dear Healthcare Professional,

**Re: Possible interaction between clopidogrel and proton pump inhibitors**

The European Medicines Agency (EMA) is aware of studies suggesting that clopidogrel may be less effective in patients receiving proton pump inhibitors (PPIs). This could result in patients being at an increased risk of thrombotic events, including acute myocardial infarction (heart attack).

The new concern relates to several recently published studies examining clinical outcomes of clopidogrel users. Taken together, these studies suggest that a significant interaction might occur between clopidogrel and members of the PPI class of medicines, making clopidogrel less effective when given with these medicines. Taking all the data into account, the Agency's Committee for Medicinal Products for Human Use (CHMP) and its Pharmacovigilance Working Party (PhVWP) have recommended that the product information for all clopidogrel-containing medicines should be amended to discourage concomitant use of PPI and clopidogrel-containing medicines unless absolutely necessary. Accordingly, the marketing authorisation holders for the clopidogrel-containing medicines will shortly be submitting variation applications in order to amend the product information.

The Medicines Authority has participated in these discussions held at the EMA and is in agreement with the [public statement](#) issued by the EMA, attached here for your perusal.

*Healthcare professionals are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.*